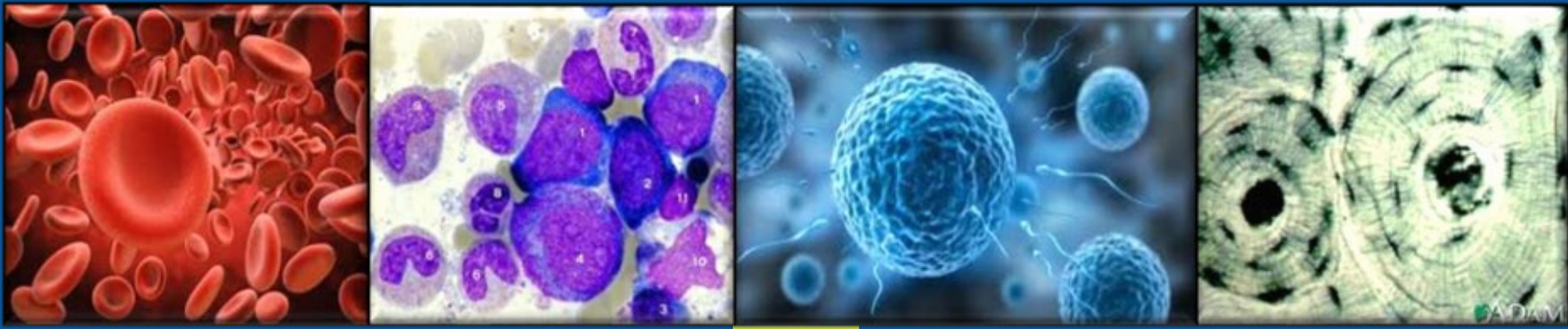


## HS-g-22-18.01 Joint Action

**Piloting a new model approach for assessing and authorising novel Blood, Tissues and Cells (BTC) preparation processes)**



# Policy context and objectives

3<sup>rd</sup> EU HP Joint Action – facilitating the authorisation of preparation process for blood, tissues and cells (GAPP)

→ Concept for common tailored approach to authorize new Blood, Tissue and Cells preparations (BTC)

- Risk assessment, proportionate clinical evidence, conditional authorization
- 15 MS authorities + 2 key professional societies

→ Facilitates access to safe and effective innovative BTC therapies

EU4Health objective: availability crisis-related products, support innovation

Other contextual factors: COVID crisis, revision/future-proof BTC legislation

# Objectives and expected outcomes

- Test and refine the GAPP methodology for...
  - new developments in different BTC subsectors (blood and plasma for transfusion, tissues for transplantation, cells for transplantation and gametes for reproductive medicine).
  - For use by professionals and by authorities
- Pilot cases => learnings and recommendations on
  - Applicability in all Member States (challenges and success-factors)
  - Different levels of risk (negligible, low, medium, high)
  - Cross-country applications
  - Cross-country assessments

# Considerations and practical points

- (this action excludes advanced therapy medicinal products)
- (this action excludes ICT developments)
- Observers from other, relevant legal frameworks (e.g., clinical trials)
  
- Direct grant to Member States
- Deadline Q4/2022
- Budget EUR 1 500 000
- HADEA